

Serial No. 08/384,248  
Atty. Docket No.: 3495.0008-08

The Examiner alleges that the specification fails to clearly demonstrate that applicants had generated the claimed antigens and antibodies at the time of filing of the application. The Examiner contends that the specification fails to provide any demonstrative evidence that applicants had generated expression vectors containing the claimed inserts, transfected suitable hosts, and produced suitable levels of recombinant HIV-1 proteins. The Examiner further contends that the specification fails to provide any evidence that these antigens were used to immunize animals and that HIV-1-specific antibodies were actually generated. At the same time, the Examiner admits that the skilled artisan, at the time of filing, provided with a restriction fragment capable of encoding a known antigen, could express and purify the antigen of interest and employ this antigen to generate antigen specific antibodies.

Applicants respectfully traverse the rejection. Applicants respectfully submit that the Examiner is not applying the appropriate standard under 35 U.S.C. § 112, first paragraph. As described in M.P.E.P. § 2163.02, the test for sufficiency of support in a parent application is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter. Ralston Purina Co. v. Far-Mar-Co., Inc., 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985). When the original specification accomplishes that conveyance, regardless of how it accomplishes it, the essential goal of the description requirement is realized. In re Wright, 866 F.2d 422, 424, 9 U.S.P.Q. 2d 1649, 1651

LAW OFFICES  
FINNEGAN, HENDERSON,  
FARABOW, GARRETT,  
& DUNNER, L.L.P.  
1300 I STREET, N.W.  
WASHINGTON, DC 20005  
202-408-4000

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(Fed. Cir. 1989). Applicants submit that the claimed **method** was fully conveyed to the skilled artisan by the teachings of the specification.

The specification provides literal support and guidance for the claimed **method**. As detailed in the December 1, 1997, Response, the specification teaches that the  $\lambda$ -J19 restriction fragments encode HIV-1 antigens. The  $\lambda$ -J19 clone was deposited at C.N.C.M. (Specification at 14.) The specification provides a detailed restriction map of the  $\lambda$ -J19 clone. Id. at Figure 2. As detailed in the December 1, 1997, Response, the specification teaches methods of expressing HIV-1 antigens encoded by restriction fragments of the  $\lambda$ -J19 clone. The specification teaches that these antigens can be used as immunogens (i.e. to produce antibodies). (Id. at 14.) Therefore, applicants submit that the claimed **method** is reasonably conveyed to the skilled artisan by the specification. Accordingly, applicants submit that the written description requirement under 35 U.S.C. § 112 has been fulfilled.

The Examiner requires experimental evidence of the generation of HIV-1 antigens, antibodies, expression vectors, transfected hosts, and immunized animals at the time of the filing date. Applicants respectfully submit that such a showing is not required under 35 U.S.C. § 112, first paragraph. First, the mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it. Gould v. Quigg, 822 F.2d 1074, 1078, 3 U.S.P.Q. 2d 1302, 1304 (Fed. Cir. 1987). Furthermore, a specification need not

LAW OFFICES  
FINNEGAN, HENDERSON,  
FARABOW, GARRETT,  
& DUNNER, L.L.P.  
1300 I STREET, N.W.  
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contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In re Borkowski, 433 F.2d 904, 908, 164 U.S.P.Q. 642, 645 (C.C.P.A. 1970). Applicants respectfully submit that the Examiner's requirement for a showing of a working example is inconsistent with the court's decisions that such experimental evidence is not required.

In addition, applicants submit that the claimed **method** is disclosed in such a manner that one skilled in the art would be able to practice it without an undue amount of experimentation. See Id. As described above, that applicants had possession of the claimed **method** is conveyed to the skilled artisan by the specification. Furthermore, the Examiner appears to have acknowledged that the specification is enabling for the claimed **method**. Paper No. 31 at 2, lines 25-30. Accordingly, applicants respectfully submit that the requirements under 35 U.S.C. § 112, first paragraph, have been fulfilled, and request withdrawal of the rejection.

For the foregoing reasons, applicants believe that this application is now in condition for allowance. In the event the Examiner disagrees, he is invited to call the undersigned to discuss the remaining issues.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an

LAW OFFICES  
FINNEGAN, HENDERSON,  
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& DUNNER, L.L.P.  
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extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested, and the fee should also be charged to our Deposit Account.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

By: 

Kenneth J. Meyers  
Reg. No. 25,146

Dated: August 3, 1998

LAW OFFICES  
FINNEGAN, HENDERSON,  
FARABOW, GARRETT,  
& DUNNER, L.L.P.  
1300 I STREET, N.W.  
WASHINGTON, DC 20005  
202-408-4000